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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
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[REDACTED] EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	18

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n No.</b> 09/684,026	<b>Applicant(s)</b> DEVICO ET AL.
	<b>Examiner</b> Ulrike Winkler, Ph.D.	<b>Art Unit</b> 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 23 July 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-3,6-16 and 18-72 is/are pending in the application.
- 4a) Of the above claim(s) 18-23 and 25-72 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 6-16 and 24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All
    - b) Some \*
    - c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
    - a) The translation of the foreign language provisional application has been received.
  - 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892)                               | <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | <input type="checkbox"/> Other: _____                                     |

### **DETAILED ACTION**

The Amendment filed July 23, 2002 (Paper No. 15) in response to the Office Action of April 23, 2002 is acknowledged and has been entered. Claims 4, 5 and 17 have been cancelled. Claims 1-3, 6-16 and 24 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 16, is attached to the instant Office Action.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-17 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**. It was not clear what is meant by "bind each other", the rejection is withdrawn in view of the claim amendments.

The rejection of claims 1-17, and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**. It was not clear what applicant intended by a "chimeric polypeptide", the claim amendments clarify that a chimeric protein with an amino acid linker is intended.

The rejection of claims 1 and 17 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimera between CD4 and gp120, does not reasonably provide enablement for a chimera utilizing a peptide mimetic spacer **is withdrawn** in view the amendments to the claims .

***Claim Rejections - 35 USC § 102***

The rejection of claims 1 and 24 under 35 U.S.C. 102(b) as being anticipated by Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999) **is withdrawn** in view of applicant's amendments to the claims.

The rejection of claims 1-8, 10, 11 and 24 under 35 U.S.C. 102(b) as being anticipated by DeVico et al. (U.S. Pat. No. 5,518,723, IDS) or DeVico et al. (U.S. Pat. No. 5,843,454, IDS) **is withdrawn** in view of applicant's amendments to the claims.

***Double Patenting***

The rejection of claims 1-8, 10, 11 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,518,723 **is withdrawn** in view of applicant's amendments to the claims.

The rejection of claims 1-8, 10, 11 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,843,454 **is withdrawn** in view of applicant's amendments to the claims.

New rejections necessitated by applicants amendments:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chackerian et al. (Proceeding of the National Academy of Sciences, March 1999) and DeVico et al. (U.S. Pat. No. 5,843,454, IDS).

The instant invention is directed to a chimeric polypeptide comprising a viral coat polypeptide from a retrovirus and a viral receptor. The sequences are linked by an amino acid spacer . The chimeric polypeptide forms a folded complex.

Chackerian et al. disclose chimeric L1-CCR5 proteins, L1 is the viral capsid protein from bovine papillomavirus type-1 and CCR5 is a cell surface receptor and a coreceptor for some HIV strains. The reference teaches that antibodies raised to L1-CCR5 were effective at blocking viral infection in M-tropic virus strain using a single cycle replication assay ( p 2376, column 2, 1<sup>st</sup> paragraph). The chimera comprises viral coat sequences and viral receptor sequences, the reference makes no discussion of using spacer amino acids yet the chimera is able to form the requisite tertiary structure indicating that a spacer is not required for the structure. That conformation is an important aspect in these chimera is indicated by the fact that denatured L1-CCR5 chimeras did not induce antibody formation to CCR5, only in the context of the folded complex is there antibody production against the receptor. This is an important point because the

host should ordinarily not produce auto-antibodies against a host receptor unless the receptor is conformationally changed due to the interaction with the virus. The reference does not teach a chimera of a retrovirus coat protein and a viral receptor protein linked by spacer amino acids.

DeVico et al. disclose in both patents a CD4-gp120 complex that have been covalently linked using a reactive spacer molecule. The reference teaches using the complex as a vaccine. The reference teaches that the interaction between the virus coat protein and the virus receptor exposes cryptic epitopes that are not present with the viral coat protein or the CD4 receptor alone (see table 1). Gp120 and CD4 have an affinity for one another and spontaneously form a complex when placed in a solution together. The reference does not teach using an amino acid spacer in the production of the antigenic complex.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a chimera for the production of the gp120-CD4 complex. The chimera as taught by Chackerian et al. requires the single process step utilizing affinity purification after the expression of the chimera in an insect cell. One having ordinary skill in the art would have been motivated to make a gp120-CD4 chimera to achieve the conformational complex as taught by DeVico et al. which would have the advantage of requiring less process steps in order to achieve the same function. The prior art requires purifying the CD4 and the gp120 proteins separately allowing them to interact and then chemically cross linking followed by the removal of the excess cross linker. One having ordinary skill in the art would have a high expectation of success when expressing the complex as a single polypeptide. The addition of amino acid linkers would have been obvious to the ordinary artisan in order to alleviate potential folding

constraints in the chimera. Therefore, the instant invention is obvious over Chackerian et al. and DeVico et al.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

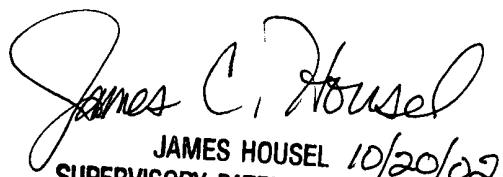
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
JAMES HOUSEL 10/20/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600